METHODS AND APPARATUS FOR TREATMENT OF EYE DISORDERS USING ARTICULATED-ARM-COUPLED ULTRAVIOLET LASERS

J. T. Lin (filed on 8/21/03)

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to methods and apparatus for the treatment of presbyopia and glaucoma using articulated-arm-coupled ultraviolet laser to ablate the sclera tissue.

2. Prior Art

Corneal reshaping including a procedure called photorefractive keratectomy (PRK) and a new procedure called laser assisted in situ keratomileusis, or laser intrastroma keratomileusis (LASIK) have been performed by lasers in the ultraviolet (UV) wavelength of (193 - 213) nm. The commercial UV refractive lasers include ArF excimer laser (at 193 nm) and other non-excimer, solid-state lasers such as those proposed by the present inventor in 1992 (US pat. no. 5,144,630) and in 1996 (US pat. No. 5,520,679). The above-described prior arts using lasers to reshape the corneal surface curvature, however, are limited to the corrections of myopia, hyperopia and astigmatism.

Refractive surgery using a scanning device and lasers in the mid-infrared (mid-IR) wavelength was first proposed by the present inventor in US Pat. No. 5,144,630 and 5,520,679 and later proposed by Telfair et. al., in US Pat. No. 5,782,822, where the generation of mid-IR wavelength of (2.5-3.2) microns were disclosed by various methods including: the Er:YAG laser (at 2.94 microns), the Raman-shifted solid state lasers (at 2.7-3.2 microns) and the optical parametric oscillation (OPO) lasers (at 2.7-3.2 microns).[a]

Corneal reshaping may also be performed by laser thermal coagulation currently conducted by a Ho:YAG laser (at about 2 microns in wavelength) proposed by Sand in US Pat. 5,484,432. This method, however, was limited to

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low-diopter hyperopic corrections. Strictly speaking this prior art did not correction the true "presbyopia" and only performed the mono-vision for hyperopic patients. A thermal laser is required and the laser treated area was within the optical zone diameters of about 7 mm.

Ruiz in US pat. No. 5,533,997 proposed the use of laser ablation of cornea surface to correct presbyopic patients. This prior art, however, must generate multifocal (or bifocal) surface on the central portion of the cornea in order to achieve the desired presbyopia correction. Corneal curvature change by laser ablation in this prior art, however, did not actually resolve the intrinsic problems of presbyopic patient caused by age where the cornea lens loss its accommodation as a result of loss of elasticity due to age.

All the above-described prior arts are using methods to change the cornea surface curvature either by tissue ablation (such as in UV laser) or by thermal shrinkage (such as in Ho:YAG laser) and all are using lasers onto the central potion of the cornea.

The alternative method for presbyopia correction, therefore, is to increase the accommodation of the presbyopic patients by change the intrinsic properties of the sclera and ciliary tissue to increase the lens accommodation without changing the cornea curvature. This method of sclera ablation is fundamentally different from all the prior arts including that of Ruiz, in which reshaping cornea curvature into multifocal shape was required for presbyopia correction.

To treat presbyopic patients, or the reversal of presbyopia, using the concept of expanding the sclera by mechanical devices has been proposed by Schachar in U.S. patents 5,489,299, 5,722,952, 5,465,737 and 5,354,331. These mechanical approaches have the drawbacks of complexity and are time consuming, costly and have potential side effects. To treat presbyopia, the Schachar patents Nos. 5,529,076 and 5,722,952 propose the use of heat or radiation on the corneal epithelium to arrest the growth of the crystalline lens and also propose the use of lasers to ablate portions of the thickness of the sclera. However, these prior arts do not present any details or practical methods or laser parameters for the presbyopic corrections. No clinical studies have been practiced to show the effectiveness of the proposed concepts. The concepts proposed in the Schachar patents, 5,354,331 and 5,489,299, regarding lasers suitable for ablating the sclera tissues were incorrect because he did not identify which lasers are "cold lasers". Many of his proposed lasers

are thermal lasers which will cause thermal burning of the cornea, rather than tissue ablation. Furthermore, the clinical issues, such as locations, patterns and depth of the sclera tissue removal were not indicated in these prior patents. In addition, it is essential to use a scanning or fiber-coupled laser to achieve the desired ablation pattern and to control the ablation depth on the sclera tissue. Schachar's methods also require the weakening of the sclera and increase its diameter by expansion, whereas the proposed concept of the present invention provides new mechanisms for accommodation.

The "presbyopia" correction proposed by Ruitz (US Pat. No. 5,533,997) using an excimer (ArF) laser also required the corneal surface to be reshaped to form "multifocal" effort for a presbyopia patents to see near and far. However, Ruitz's "presbyopia" correction is fundamentally different from that of the present patent which does not change the corneal curvature. The presbyopia correction proposed in the present patent is to increase patient's accommodation rather than reshaping the cornea into "multifocal" surface.

The technique used in the prior art of Bille (Pat. No. 4,907,586) required a quasi- continuous laser having pulse duration less than 10 picoseconds and focused spot less than 10 micron diameter and the laser is confined to the interior of a selected tissue to correct myopia, hyperopia or astigmatism. Bille also proposed the laser to focus into the lens of an eye to prevent presbyopia. This prior art system is very complicate and needs a precise control of the laser beam size and focusing position. Furthermore, clinical risk of cataract may occur when laser is applied into the lens area.

Another prior art proposed by Spencer Thornton (Chapter 4, "Surgery for hyperopia and presbyopia", edited by Neal Sher (Williams & Wilkins, MD, 1997) is to use a diamond knife to incise radial cuts around the limbus areas. It requires a deep (90%-98%) cut of the sclera tissue in order to obtain accommodation of the lens. This method, however, involves a lot of bleeding and is difficult to control the depth of the cut which requires extensive surgeon's skill. Another drawback for presbyopia correction provided by the above-described incision methods is the major post-operative regression of about (30%-80%). And this regression is minimum in the laser-ablation method proposed in the present invention. We note that there is intrinsic difference between the ablation-method proposed in this invention and the knife-incision. The sclera space produced by the incision method is not permanent and may be greatly reduced during the tissue healing and cause the regression. This

major source of regression in incision method however will not occur in the laser or non-laser ablation-methods as proposed in this invention, where portion of the sclera tissue is permanently removed.

One of the important concepts proposed in the present invention is to support the post-operative results which show minimum regression. We proposed that the laser ablated sclera tissue "gap" will be filled in by the sub-conjunctival tissue within few days after the surgery. This filled in sub-conjunctival tissue is much more flexible than the original sclera tissue. Therefore the filled-in gap in the sclera area will cause the under laying ciliary body to have more space to move. This in turn will allow the ciliary body to contract or expand the zonular fiber which is connected to the lens, when the presbyopic patient is adjusting his lens curvature to see near and far. The above described sub-conjunctival tissue filling effects and the increase of "flexibility" of the sclera area are fundamentally different from the scleral "expansion"(or weakening) concept proposed by the prior arts of Schachar and proposed by the implant of a scleral band. In the present invention, the laser ablated sclera area is not weakening, it becomes more flexible instead.

The prior art by the present inventor, US Pat. No. 6,263,879 was limited to scanning device which has drawback of de-centration caused by eye movement, and it is hard to control the ablation depth due to the fact that the scanning laser beam is not perpendicular to the scleral surface. Another prior art of Lin, US Pat. No. 6,258,082 proposed the fiber-coupled lasers which however was mainly designed for an IR-laser because the coupling efficiency of existing fibers was very poor, less than 30% when laser wavelength shorter than 0.27 microns.

In addition, the fiber-coupled laser has drawbacks of high fiber cost and the fiber is easy to break, in which the fiber tip was contacted to the scleral which caused tissue to stick to the tip and cleaning is required during the surgery. No high UV-transparent fibers are currently available for the application of high peak-power UV lasers, particularly for the spectral range of (0.19 – 0.3) microns, operated in the nanosecond pulse duration.

Articulated arms have been commercially used to deliver laser beams. However, they are mainly used for dermatological uses and are limited to spectrum of visible (500-700) nm and IR (1-3) microns. No UV lasers of (190-300) nm have been developed and coupled to articulated arm for the treatment of eye disorders including presbyopia and glaucoma. Furthermore, the

articulated arm for prior art uses did not require a good beam alignment or centration, because of a rather large beam spot (4-15) mm, are normally used. On the contrary, the presently proposed UV laser, articulated-arm system requires centration/alignment better than 0.2 mm because of its much smaller beam spot of (0.2-1.0) mm needed in the present invention. The dermatological lasers are using the laser thermal effects to change the skin conditions, whereas the present invention requires a "cold" laser for tissue ablation and thermal effects must be minimized.

One objective of the present invention is to provide an apparatus and method to obviate these drawbacks in the prior arts.

It is yet another objective of the present invention to use an articulated-arm-coupled lasers such that the degree of vision accommodation can be controlled by the ablation patterns, location, size and shapes of the removed sclera tissue.

It is yet another objective of the present invention to define the non-thermal lasers for efficient tissue ablation to present refractive power change of the cornea caused by thermal effects.

It is yet another objective of the present invention to define the optimal laser parameters and the ablation patterns for best clinical outcome for presbyopia patients, where sclera ablation will increase the accommodation of the ciliary muscle by the increase of the flexibility in the laser-ablated areas.

It is yet another objective of the present invention to provide the appropriate ablation patterns which will cause effective ciliary body contraction and expansion on the zonules and the lens.

It is yet another objective of the present invention to provide a new mechanism_which supports the clinical results of presbyopia correction with minimum regression. One important concept proposed in the present invention is to support the post-operative results which show minimum regression when presbyopia is corrected by a laser ablation for the sclera tissue.

We proposed that the laser ablated sclera tissue "gap" will be filled in by the sub-conjunctival tissue within few days after the surgery. This filled in sub-conjunctival tissue is much more flexible than the original sclera tissue. Therefore the filled-in gap in the sclera area will cause the underlaying ciliary body becomes more flexible. This will allow the ciliary body to contract or expand the zonular fiber connected to the lens when the presbyopic patient is adjusting his lens curvature to see near and far.

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It is yet another objective of the present invention to provide a 2-component model to count for the total accommodation amplitude for treated presbyopia patients.

It is yet another objective of the present invention to provide an articulated-arm device to achieve the coupling efficiency required in sclera ablation.

The present invention described in great detail for the treatment of presbyopia may be extended to other eye disorders including glaucoma. For the case of glaucoma, the laser may be used to remove sclera tissue in the area where Schlemm's channel is located followed by a removal of a small portion of the iris underlying this area.

The invention having now been fully described, it should be understood that it may be embodied in other specific forms or variations without departing from the spirit or essential characteristics of the present invention. Accordingly, the embodiments described herein are to be considered to be illustrative and not restrictive.

SUMMARY OF THE INVENTION

The preferred embodiments of the basic surgical lasers of the present invention shall include ultraviolet (UV) lasers having wavelength range of about (190 – 360) nm, such as ArF (at 193 nm) and XeCl (at 308 nm) excimer lasers, nitrogen laser (at 337 nm) flash-lamp-pumped and diode-pumped solid state lasers having wavelength range of about (190-355) nm such as Nd-YAF, Er:YAG, Nd:YAG, Er:glass and Ti:saphire laser using harmonic generation from nonlinear crystals of KTP, BBO, LBO, KDP and other UV transparent crystals.

It is yet another preferred embodiment is to couple the basic lasers by an articulated-arm to deliver the laser beam to treated area of the eye, in which the end of the arm is connected to a short tip-tube which may be disconnected for reuse after sterilization.

It is yet another preferred embodiment to use a 2-component model to estimate the post-operation accommodation improvement which is given by lens relaxation and anterior shift.

It is yet another preferred embodiment to focus the laser beams into a desired spot size on the treated area of the eye. Various ablation patterns may be generated manually via the hand piece including multiple rings of spots, radial line or non-specific shapes outside the limbus.

It is yet another preferred embodiment to control laser beam spot size by position and focal length of focusing lens and the length of the attached end pieces.

It is yet another preferred embodiment is to ablate by the basic UV lasers, a portion of the sclera tissue to increase the flexibility and available space of the sclera-ciliary-zonus complex to increase the lens accommodation (for presbyopia) and reduce the intraocular pressure (IOP) of the eye (for glaucoma treatment).

It is yet another preferred embodiment to open the conjunctiva layer prior to the laser ablation of the under-layer of the sclera tissue for a better control of the ablation depth and for safety reasons.

It is yet another preferred embodiment is that the conjunctiva layer may also be ablated by the UV laser without open it as a flap in order to speed up the surgical procedure.

Further preferred embodiments of the present invention will become apparent from the description of the invention which follows.

DETAILED DESCRIPTION OF THE INVENTION AND THE PREFERRED EMBODIMENTS

A surgical laser system in accordance with the present invention comprises a basic laser having wavelength in the UV spectrum is focused and coupled to an articulated-arm (ATA) which is commercially available except the use of UV 45 degree high reflecting coated mirrors which are mounted to each

of the joints. These mounts are independently adjustable for fine-tuning of laser alignment and centration. The preferred ATA is attached to an end piece which is used to contact the treated eye surface such that laser beam spot size and its location are well defined. Using high reflecting UV mirrors, we are able to achieve an overall coupling efficiency over 75% when an articulated-arm having 4 joints is used. This efficiency is much higher than that of a fiber is used, less than 30% for spectrum range of (195-280) nm.

The proposed UV laser provides a "clean" cut with almost no thermal tissue damage, whereas prior art using an IR laser (LIN, US Apt. 6,258,082) at about 2.9 microns suffers certain degree of thermal damage, particularly around the laser spot edge which has less power. It is critical that thermal effects on the cornea must be minimized, otherwise patient's far vision will become "hyperopic shift" caused by the thermal shrinkage of the cornea. This drawback of prior art IR laser is totally eliminated when the proposed UV laser is used. Prior arts using a fiber and a fiber tip to deliver the laser energy also suffers fiber-tip damage when laser heating is accumulated at the tip end, unless it is efficiently transported to the treated tissue. IR fiber is also easy to break and its tip end can be easily stuck with sclera tissue and cause available laser power to drop significantly. All these prior art drawbacks are obviated in the proposed UV laser system coupled to an articulated arm which also has a much higher coupling efficiency than that of an IR laser.

The preferred articulated arm shall have a length about (0.5-1.2) meter, a minimum of 2 joints (for free rotation in x, y and z directions), connected to an end piece with length about (5-20) mm. In addition, at least 2 highly UV reflecting mirrors are 45 degree mounted at the joint position to reflect the laser beam along the arm tube with a centration better than 0.2mm. The preferred laser spot diameter is about (0.2-1.0) mm with UV energy per pulse of about (0.5-10)mJ on the sclera surface, or at the output end of the articulated arm. It is also a preferred requirement that the laser output alignment from the arm should not deviate more than 0.2mm while keeping its power level over 85% of the perfectly centered position, when the arm is freely rotated in 3 dimension.

According to the present invention, the preferred embodiments of the basic surgical lasers for presbyopia correction and/or glaucoma procedures shall include: (a) ultraviolet (UV) lasers having wavelength range of about (190 – 360) nm, such as ArF (at 193 nm) and XeCl (at 308 nm) excimer lasers, nitrogen laser (at 337 nm) and (b) solid-state lasers using harmonic generation

from solid-state lasers of Nd:YAG, Nd:YLF and Alexandrite lasers where nonlinear crystals of KTP, BBO or KDP may be used to up convert the fundamental frequency to the desired UV range. These solid-state lasers may be flash lamp pumped or diode laser pumped.

According to one aspect of the present invention, the preferable UV laser energy per pulse on scleral surface is about (0.5-10) mJ. Focused spot size of about (0.1-1.0) mm in diameter on the scleral plane is achieved by means of focusing which consists of at least one spherical lens with focal length of (5-100) cm. The other preferred laser parameter of this invention is the laser repetition rate range of about (5-100) Hz which will provide reasonable surgical speed and minimum thermal effects. The focused beam delivered to the articulated arm may be scanned over the scleral surface to_ablate various patterns by surgeon's control of the hand piece.

Another preferred embodiment is to use a cylinder focusing lens to generate slit shape size of (0.1-0.5) x (3-5) mm.

The preferred patterns of this invention include a ring-spot having at least one ring with at least 3 spots in each ring, a radial-pattern having at least 3 radials or non-specific shapes as far as it is in a symmetric form. The preferred area of the ablation is defined within two circles having diameters about 10 mm and 14 mm posterior to the limbus along the radial direction of the cornea. We should note that for the case of a circular laser spot, a radial ablation pattern on the scleral surface may be generated either by manually scan the end tip by a surgeon who hold the hand piece. For the situation of the slit spot, the surgeon may easily generate the radial patterns without moving the end tip of the articulated arm.

The preferred ablation depth of the sclera tissue is about (400-700) microns with each of the radial length of about (2.5 - 5.0) mm adjustable according to the optimal clinical outcomes including minimum regression and maximum accommodation for the presbyopic patients. The preferred radial ablation shall start at a distance about (4.0 – 5.5) mm from the corneal center and extended about (2.0-5.0) mm outside the limbus. The preferred embodiments of the radial patterns on the sclera area include at least 3 radial lines, curved lines, ring-dots or any non-specific shapes as far as they are symmetric to the center of the eye. The symmetric form is required to achieve an even "force" acting on the zonus fiber for lens relaxation. Any other non-

specific patterns including curved lines, z-shape, t-shape lines around the area outside the limbus should be within the scope of this patent.

It is yet another preferred embodiment is to control the laser spot on the sclera surface by positioning of the focusing lens at about one focal length away from the output end of the articulated arm. This focal lens is preferred to be integrated inside the last section (last joint) of the arm having a typical length about (5-20) cm. For safety issue, the preferred laser beam is focused (0.5-1.5) cm above the sclera surface such that the beam is divergent when delivered to the sclera surface. When surgeon's hand piece is held away from the eye surface, the laser beam spot is always divergent and expanding to a low power level. High power ablating spot is available only when end-top of the articulated arm is contacted to the eye surface.

It is yet another preferred embodiment is to ablate a portion of the sclera tissue for the treatment of eye disorders including prebyopia, (by increasing accommodation) and glaucoma (by reducing the intraocular pressure). In each procedure, the sclera-ciliary complex becomes more flexible with increasing space between the ciliary ring and the lens. For quantitative discussion, we propose the following. Let AA stands for the accommodation amplitude (AA) increase after the surgery, and then the total amount of AA is given by both lens relaxation (LR) and lens anterior shift (LAS) as follows:

$$AA = -m(dS) + M\,(dT)$$

Where dS and dT stand for the amount of anterior shift and lens thickness increase due to its curvature changes (curvature radius R1 and R2 decrease) when the zonus relaxes. M and m are the slopes for the AA versus LR and LAS. Our calculations show that m = (1.0-1.7)/D/mm depending on the initial lens curvatures. The slope for IR effect is given by M = 435/WS, where WS is the square of the lens optical zone diameter (W). For W= (4.0-5.5) mm, we obtain M= (14.4-27.2) (D/mm) which is about (15-27) times of m.

There are several important implications may be addressed based on this new model: (1) the total accommodation AA is the sum of 2 components m (due to LAS) and M (due to LR); however, the effect from M is much higher than that of m; (2) for aged eyes with deformable lens capsule presbyopia may be treated mainly by the LR component; (3) AS component will be the only mechanism for the increase of AA when the lens capsule is extremely rigid caused by age.

The mechanism of accommodation proposed by Schachar (US pat. 5,354,331 and 5,489,299) was based on the increase of ciliary ring diameter for lens relaxation. These prior arts are in conflict with recently reported data based on MRI imaging measurements. In addition, the second component of LAS for accommodation has never been proposed in any of prior arts. During accommodation, the ciliary body, based on the present new theory, is actually contracted inward to the lens (or ciliary ring diameter decreases) and also forward to the anterior chamber (or its depth decreases), noting that dS is negative and dT is positive and AA is the sum of both components for accommodation. Without using this proposed new mechanism, sclera ablation would not be able to treat patients with rigid lens capsule. This new mechanism is also able to explain the clinical results in our old, patients, say, age over 60.

While the invention has been shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that the foregoing and other changes and variations in form and detail may be made therein without departing from the spirit, scope and teaching of the invention. Accordingly, threshold and apparatus, the ophthalmic applications herein disclosed are to be considered merely as illustrative and the invention is to be limited only as set forth in the claims.